



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,382	09/09/2004	Jian Luo	MGC020325	6441
7590		02/21/2008	EXAMINER	
Jian Luo		DICKINSON, PAUL W		
240 Klamath Street		ART UNIT		
Brisbane, CA 94005		PAPER NUMBER		
		1618		
		MAIL DATE		
		DELIVERY MODE		
		02/21/2008		
		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/507,382	Applicant(s) LUO ET AL.	
	Examiner PAUL DICKINSON	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/31/2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 12/31/2007, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objects are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Claims 1-10 are pending. Claims 1-4 and 7-10 are currently under consideration.

Response to Arguments

Claim Rejections - 35 USC § 112

Art Unit: 1618

Claims 4 and 8 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The range limitation in Claim 4 is vague and indefinite. The phrase "administered... at about the same time" in Claim 8 is vague and indefinite.

Applicant proposes to divide Claim 4 into two new claims, one claim directed to the broader range and one claim directed to the narrower claim. Applicant proposes to amend Claim 8 to clarify that the administration is "at the same time or at a different time within 48 hours."

Applicant's arguments have been fully considered. The proposed changes would overcome the above rejections. These are only proposed changes, however, and Applicant has not submitted a new set of amended claims, which are required to overcome the above rejections. Applicant's arguments, without a set of amended claims, are not found persuasive. The rejection of Claims 4 and 8 under 35 U.S.C. 112, second paragraph, is maintained.

Claim Rejections - 35 USC § 102

Claims 1-3, 7, 9-10 were rejected under 35 U.S.C. 102(b) as being anticipated by Paterniti et al (WO9805331).

Applicant argues that Paterniti et al teach that all pharmaceutical effects are resulted from the combination of (a) PPARgamma agonist and (b) PPARalpha agonist. Paterniti et al does not provide any teaching, suggestion, or anticipation that any one of

Art Unit: 1618

the two main components (a) PPARgamma and (b) PPARalpha agonist alone will exert any pharmaceutical effect when combined with metformin. The present invention is related to a pharmaceutical composition contains only members of PPARalpha agonist (gemfibrozil or ciprofibrate) and metformin. The present invention does not require PPARgamma agonist.

The Examiner agrees that the pharmaceutical composition disclosed by Paterniti et al comprises a PPARgamma agonist. The Examiner reiterates what was stated in the office action mailed 10/2/2007, that Applicant uses open terminology in the instant claims (page 6, first full paragraph) which does not exclude additional, non recited components, such as PPARgamma agonist. Specifically, the transitional term "comprising" in Instant Claim 1 is inclusive or open-ended. If Applicant wishes to claim as their invention a composition which is composed of exclusively (a) a glucose-lowering agent metformin in one of its pharmaceutically acceptable forms and (2) a lipid-improving agent selected from non-glucose-lowering fibrates, excluding any non-recited elements, this should be reflected in the claims using closed language.

The rejection of Claims 1-3, 7, 9-10 under 35 U.S.C. 102(b) as being anticipated by Paterniti et al (WO9805331) is maintained.

Claim Rejections - 35 USC § 103

Claim 4 was rejected under 35 U.S.C. 103(a) as being unpatentable over Paterniti et al (see above).

Applicant argues that Paterniti et al teaches that all pharmaceutical effects are resulted from the combination of (a) PPARgamma agonist and (b) PPARalpha agonist. Paterniti et al does not provide any teaching, suggestion, or anticipation that any one of the two main components (a) PPARgamma and (b) PPARalpha agonist alone will exert any pharmaceutical effect when combined with metformin. The present invention is related to a pharmaceutical composition contains only members of PPARalpha agonist (gemfibrozil or ciprofibrate) and metformin. The present invention does not require PPARgamma agonist.

As stated above, The Examiner agrees that the pharmaceutical composition disclosed by Paterniti et al comprises a PPARgamma agonist. If Applicant wishes to claim as their invention a composition which is composed of exclusively (a) a glucose-lowering agent metformin in one of its pharmaceutically acceptable forms and (2) a lipid-improving agent selected from non-glucose-lowering fibrates, excluding any non-recited elements, this should be reflected in the claims using closed language.

The rejection of Claim 4 under 35 U.S.C. 103(a) as being unpatentable over Paterniti et al is maintained.

Claim 8 was rejected under 35 U.S.C. 103(a) as being unpatentable over Barelli et al (US 5922769) in view of Ko et al.

One skilled in the art would not be able to envisage the present invention based on the teachings of Barelli et al and Ko et al, especially, the fact that gemfibrozil failed to have any significant effect on plasma glucose levels in patients with type 2 diabetes. In

Art Unit: 1618

the present invention, the combined administration of metformin and gemfibrozil produced an unexpected synergistic reduction of plasma glucose concentrations. Applicant argues that Ko et al confirms the efficacy gemfibrozil in lowering triglyceride levels and raising HDL-C levels in patients with type 2 diabetes, but the drug fails to have any significant effect on plasma glucose levels.

The arguments have been fully considered but are not deemed persuasive. As stated in the office action, both metformin and gemfibrozil are administered to treat diabetes mellitus. The two drugs have overlapping patient populations, and therefore administration of both of these drugs, at about the same time, would have been obvious to one skilled in the art. Applicant is arguing as their invention an unexpected synergistic effect between the two above compounds in reducing plasma glucose concentrations, but this is not reflected in the instant claim. Instant Claim 8, which depends from Instant Claim 1, uses open terminology. The invention, as claimed, does not exclude the presence of other active components. Furthermore, Applicant argues as their invention an unexpected synergism between metformin and gemfibrozil. Applicant has provided data that supports a synergistic effect between metformin and gemfibrozil when administered in the same composition (see Appendix to the Specification, Tables 1-2). There is, however, no data to support the synergistic effect of administration of the two compounds at every time interval that is encompassed by "about the same time." Applicant is reminded that no new amended claims have been submitted.

Art Unit: 1618

The rejection of Claim 8 under 35 U.S.C. 103(a) as being unpatentable over Barelli et al in view of Ko et al is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1618

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Paul Dickinson
Examiner
AU 1618

February 7, 2008



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER